DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 8, 2015

FreeRider Corporation
Aaron Chang, Operations Manager
FreeRider USA
8696 Utica Avenue
Rancho Cucamonga, CA 91730

Re: K133187
Trade/Device Name: Freerider FR1, models FR1-13, FR1-15, FR1-17
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: November 21, 2014
Received: December 9, 2014

Dear Mr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133187

Device Name
Freerider FR1, models FR1-13, FR1-15, FR1-17

Indications for Use *(Describe)*
The device provides transportation for an elderly or disabled person. It can be used in a variety of indoor and outdoor settings.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summany

1. Contact Details

Applicant Name : Freerider Corporation
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Freerider Corporation
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Date Prepared : October 1, 2013

2. Device Name

Trade Name : Freerider FR1

Common Name : Electric scooter

Classification Name : Motorized three-wheeled vehicle; INI; 890.3800

3. Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Manufacturer
K092650	INI	HEARTWAY Power Mobility Scooter, S12	HEARTWAY Medical Products Co., Ltd.
K971387	INI	Freerider FR 510-F	Freerider Corp.

4. Device Description

The Freerider FR1 is a battery-powered, four-wheeled scooter intended to provide mobility for elderly or disabled individuals in indoor and outdoor settings. The FR1 is meant to be used by a single rider weighing up to 400 pounds. The scooter is rear-wheel drive and has electric, regenerative electromechanical brakes. It has an adjustable seat that can be removed for transport or height adjustment.

The steering and user controls are provided on the steering tiller/handlebars for ease of use by the rider. Steering is controlled simply by turning the handlebars in the desired direction. There are two thumb levers, an emergency brake, and buttons on the tiller console to control movement of the scooter.

The FR1 has a controller and 2 batteries. The controller is used on a number of other scooters that have been previously cleared. There is also an off-board battery charger, which has also been previously cleared. The specifications of battery charger is same as a predicate device, Heartway powered mobility S-12(K092650).

5. Intended Use/Indications for use

The FR1 provides transportation for an elderly or disabled person. It can be used in a variety of indoor and outdoor settings.

6. Substantial Equivalence Comparison

The FR1 is substantially equivalent to the HEARTWAY Power Mobility Scooter S12 (K092650) and the Freerider FR510-F (K971387)

The device features of the FR1, FR510-F, and the HEARTWAY S12 are very similar. All are electric scooters that are battery operated and have automatic braking systems. Batteries and battery chargers are provided with each scooter. Use parameters are very similar. The differences are as follows. The maximum weight that the FR1 can carry is higher and it has a larger turning radius.

7. Non-clinical Testing

Electromagnetic interference testing was conducted to IEC Standards, RESNA testing to multiple sections of WC-1 and WC-2 was conducted. Additional bench testing related to ground current leakage and summary matrix testing was also conducted. The FR1 passed all testing.

8. Clinical Testing

No clinical testing is included in this submission.

9. Technological Characteristics

The device features of the FR1 and its predicate devices, Freerider FR510-F and HEARTWAY S12 are very similar. All are electric scooters that are battery operated and have automatic braking systems. Batteries and battery chargers are provided with each scooter. Use parameters are very similar.

There are some differences between the FR1 and the HEARTWAY S12. One is that the FR1 is heavier and it can carry a heavier user. The HEARTWAY S12 does not have anti-tip wheels. The FR1 has three models that vary by travel range. None of these differences raises new issues of safety and effectiveness.

10.Conclusions

The safety and effectiveness of the Freerider FR1 was demonstrated by the testing in compliance with national and international standards. The intended use, basic technology, and many features of the FR1 are similar to the predicate device. No new issues of safety and effectiveness are raised by the differences between the FR1, HEARTWAY S12 and Freerider FR510-F.